

O I P E BOCKET NO.: WYNC-0716 (AM101156-1)

IFW
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Darlene C. Deecher et al.

Application No.: 10/684,777

Filing Date: October 14, 2003

Confirmation No.: 3353

Group Art Unit: 1617

Examiner: Not yet known

For: Use of Norepinephrine Reuptake Modulators for Preventing And Treating Vasomotor Symptoms

DATE OF DEPOSIT: May 20, 2004

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

Heather Kite

TYPED NAME: Heather Kite

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of

the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

- In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:
 - Certification in Accordance with § 1.97(e) is attached;
 - or
 - The fee of \$180.00 as set forth in § 1.17(p) is attached.
- In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of \$180.00 as set forth in § 1.17(p).
- Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.
- Copies of references listed on the attached Form PTO-1449 are enclosed herewith EXCEPT THAT:
 - Copies of references 46-53 listed on the attached Form PTO 1449 are not required to be submitted pursuant to the June 30, 2003 recent revisions to 37 CFR § 1.98(a)(2)(i).

In view of the voluminous nature of references 40-45, and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.

In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:

Copies of references [list as appropriate] listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No.

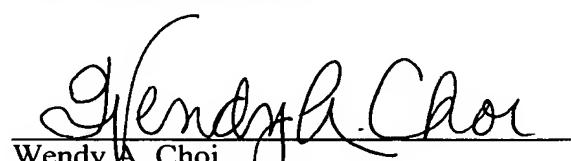
, filed .

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

Enclosed is a copy of the corresponding PCT/US03/32760 Search Report dated March 3, 2004.

There are no listed references which are not in the English language.

Date: May 20, 2004



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Form PTO-1449 Modified		Docket No. WYNC-0716/ (AM101156-1)	Application No. 10/684,777
List of Patent and Publications Cited by Applicant (Use several sheets if necessary)		Applicant Darlene C. Deecher et al.	
U.S. Department of Commerce Patent and Trademark Office		Filing Date October 14, 2003	Group 1617
		Confirmation No. 3353	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
1	Clinical Trial: "Phase III Randomized Study of Medroxyprogesterone Versus Venlafaxine in Women With Symptomatic Hot Flashes", www.clinicaltrials.gov sponsored by the National Institutes of Health, Study ID Numbers: CDR0000069217; NCCTG-N99C7; NCI-P02-0204, 2003, 6 pages		
2	Acs, N. et al., "Estrogen improves impaired musculocutaneous vascular adrenergic reactivity in pharmacologically ovariectomized rats: a potential peripheral mechanism for hot flashes?", <i>Endocrinology</i> , 2001 15: 68-73		
3	Barlow, D. H., "Venlafaxine for hot flushes," <i>Lancet</i> , 16 December 2000, 356(9247): 2025-2026		
4	Barton, D. et al., "Hot Flashes – Aetiology and Management," <i>Drugs and Aging</i> , 2001, 18(8): 597-606		
5	Berendsen, H. H. G., "Hot Flushes and serotonin," <i>Journal of the British Menopause Society</i> , March 2002, 8(1): 30-34		
6	Berendsen, H. H. G., "Effect of tibolone and raloxifene on the tail temperature of oestrogen-deficient rats," <i>European Journal of Pharmacology</i> , 2001, 419(1): 47-54		
7	Berendsen, H. H. G., "The role of serotonin in hot flushes," <i>Maturitas</i> , 2000, 36(3): 155-164		
8	Bundgaard, H., "Means to enhance penetration; Prodrugs as a means to improve the delivery of peptide drugs," <i>Advanced Drug Deliver Reviews</i> , 1992, 8, 1-38		
9	Bundgaard, H. et al., "Glycolamide Esters as Biodegradable Prodrugs of Carboxylic Acid Agents: Synthesis, Stability, Bioconversion, and Physicochemical Properties," <i>J. of Pharmaceutical Sciences</i> , April 1988, 77(4):285		
10	Casper, R. F. et al., "Neuroendocrinology of menopausal flushes: an hypothesis of flush mechanism," <i>Clinical Endocrinology</i> , 1985, 22: 293-312		
11	Fink, G. et al., "Oestrogen and mental state," <i>Nature</i> , 1996, 383(6598): 306		
12	Freedman, R. R. et al., "Clonidine raises the sweating threshold in symptomatic but not asymptomatic postmenopausal women," <i>Fertility & Sterility</i> , 2000, 74(1): 20-3		
13	Freedman, R. R., "Physiology of hot flashes," <i>American Journal of Human Biology</i> , 2001, 13: 453-464		
14	French, N., " α_2 -Adrenoceptors and I ₂ sites in the mammalian central nervous system," <i>Pharmacol. Ther.</i> , 1995, 68(2):175-208		
EXAMINER		DATE CONSIDERED	

Form PTO-1449 Modified List of Patent and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce Patent and Trademark Office	Docket No. WYNC-0716/ (AM101156-1)	Application No. 10/684,777
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	Filing Date October 14, 2003	Group 1617
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
✓ 15	Janowsky, et al., "Desipramine: an overview," <i>Journal of Clinical Psychiatry</i> , 1984 , 45(10 Pt 2): 3-9	
✓ 16	Katovich, M. J. et al., "Mechanisms mediating the thermal response to morphine withdrawal in rats", <i>Proceedings of the Society for Experimental Biology & Medicine</i> , 1990 , 193(2): 129-35	
✓ 17	Katovich, M. J. et al., "Alpha-adrenergic mediation of the tail skin temperature response to naloxone in morphine-dependent rats," <i>Brain Research</i> , 1987 , 426: 55-61	
✓ 18	Kramer et al., In: Murphy et al., <i>3rd Int'l Symposium on Recent Advances in Urological Cancer Diagnosis and Treatment-Proceedings</i> , Paris, France: SCI: 3-7 1992	
✓ 19	Krogsgaard-Larsen, et al., (ed). "Design and Application of Prodrugs, Textbook of Drug Design and Development, Chapter 5, 113-191 1991	
✓ 20	Kronenberg et al., "Thermoregulatory Physiology of Menopausal Hot Flashes: A Review," <i>Can. J. Physiol. Pharmacol.</i> , 1987 , 65:1312-1324	
✓ 21	Loprinzi, C.L. et al., "Venlafaxine in management of hot flashes in survivors of breast cancer: a randomized controlled trial," <i>Lancet</i> , December 16, 2000 , 356(9247): 2059-2063	
✓ 22	Loprinizi, C. L. et al. "Pilot Evaluation of Venlafaxine Hydrochloride for the Therapy of Hot Flashes in Cancer Survivors," <i>Journal of Clinical Oncology</i> , July 1998 , 16(7): 2377-2381	
✓ 23	Mackinnon et al., " α_2 -Adrenoceptors: more subtypes but fewer functional differences," <i>TIPS</i> , 1994 , 15: 119-123	
✓ 24	Merenthaler et al., "The effect of estrogens and antiestrogens in a rat model for hot flush," <i>Maturitas</i> , 1998 , 30(3): 307-316	
✓ 25	Morin, S. M., "Atomoxetine Selectively Induces Fos Expression in the Rat Prefrontal Cortex," Presented at Society for Neuroscience Annual Meeting (SFN); November 2-7, 2002 , Orlando, FL	
✓ 26	Pacholczyk, T. et al., "Expression cloning of a cocaine-and antidepressant-sensitive human noradrenaline transporter," <i>Nature</i> , 1991 , 350(6316): 350-4	
EXAMINER	DATE CONSIDERED	

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

✓ 27	Panek, D.U. et al., "Effect of continuous intraventricular estrogen or catechol estrogen treatment on catecholamine turnover in various brain regions," <i>J. Pharmacol. Exp. Ther.</i> , 1986, 236(3), 646-652
✓ 28	Prasad, P.D., et al., "Functional expression of the plasma membrane serotonin transporter but not the vesicular monoamine transporter in human placental trophoblasts and choriocarcinoma cells," <i>Placenta</i> , 1996, 17(4): 201-7
✓ 29	Quella, S. K. et al., "Pilot evaluation of Venlafaxine for the treatment of hot flashes in men undergoing androgen ablation therapy for prostate cancer," <i>The Journal of Urology</i> , July 1999, 162: 98-102
✓ 30	Reneric, J.Ph. et al., "Idazoxan and 8-OH-DPAT modify the behavioral effects induced by either NA, or 5-HT, or dual NA/5-HT reuptake inhibition in the rat forced swimming test," <i>Nueropsychopharmacology</i> , April 2001, 24(4): 379-390
✓ 31	Rosenberg, J. et al., "Hypothesis: pathogenesis of postmenopausal hot flush," <i>Medical Hypotheses</i> , 1991, 35: 349-350
✓ 32	Shaw, C. R., "The perimenopausal hot flash: epidemiology, physiology, and treatment," <i>Nurse Practitioner</i> , 1997, 22: 55-56, 61-66
✓ 33	Stearns, V. et al., "Hot flushes," <i>Lancet</i> , December 7, 2002, 360(9348): 1851-1861
✓ 34	Stearns, V. et al., "Paroxetine controlled release in the treatment of menopausal hot flashes," <i>JAMA</i> , 2003, 289:2827-2834
✓ 35	Stearns, V. et al., "A pilot trial assessing the efficacy of paroxetine hydrochloride (Paxil) in controlling hot flashes in breast cancer survivors," <i>Ann Oncol.</i> , 2000, 11:17-22
✓ 36	Waldinger et al., "Treatment of hot flushes with mirtazapine: four case reports," <i>Maturitas</i> , 2000, 36(3): 165-168
✓ 37	Wilens, S.H. <i>Tables of Resolving Agents and Optical Resolutions</i> , p. 268 E.L. Eliel, Ed., University of Notre Dame Press, Notre Dame, IN 1972
✓ 38	Wilens, S.H., et al., "Strategies in optical resolutions," <i>Tetrahedron</i> , 33:2725, 1977
✓ 39	Zhang, W. et al., "Synergistic Effects of Olanzapine and Other Antipsychotic Agents in Combination with Fluoxetine on Norepinephrine and Dopamine Release in Rat Prefrontal Cortex," <i>Neuropsychopharmacology</i> , 2000, 23(3): 250-262

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*	40	Eliel, E.L. <i>Stereochemistry of Carbon Compounds</i> , McGraw-Hill, NY, 1962	
*	41	<i>Remington's Pharmaceutical Sciences</i> , 17th edition, ed. Alfonoso R. Gennaro, Mack Publishing Company, Easton, PA 1985	
*	42	Bundgaard, (ed.), <i>Design of Prodrugs</i> , Elsevier 1985	
*	43	Widder, et al. (ed.), <i>Methods in Enzymology</i> , vol. 4, Academic Press 1985	
*	44	Jacques, et al., <i>Enantiomers, Racemates and Resolutions</i> Wiley Interscience, New York, 1981	
*	45	Higuchi and Stella (eds.) <i>Prodrugs as Novel Drug Delivery Systems</i> , American Chemical Society 1975	
EXAMINER		DATE CONSIDERED	

*A copy of this reference will not be forwarded to the U.S. Patent and Trademark Office since it is believed to be too voluminous and may be obtainable by the Examiner.

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U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass
	46	3,454,554	07/08/69	Biel et al.	260	239
	47	4,229,449	10/21/80	Melloni et al.	514	239.2
	48	4,310,524	01/12/82	Wiech et al.	514	217
	49	4,535,186	08/13/85	Husbands et al.	564	336
	50	4,826,844	05/02/89	Husbands et al.	514	252
	51	5,502,047	03/26/96	Kavey	514	183
	52	2002/0107249 A1	08/08/02	Wong et al.	514	238.5
	53	2002/0128173 A1	09/12/02	Wong et al.	514	1

FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO
✓	54	99/44601 A1	09/10/99	WO		
✓	55	91/18602 A1	12/12/91	WO		
✓	56	03/077897 A1	09/25/03	WO		
✓	57	02/064543 A1	08/22/02	WO		
✓	58	0 208 235 B1	01/10/90	EP		
✓	59	1 266 659 A1	12/18/02	EP		

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Examiner Initial		Document No.	Date	Name	Class	Subclass
	60	10/685,812	10/14/03	Deecheer et al.		
	61	10/685,974	10/14/03	Deecheer et al.		
	62	60/511,542	10/14/03	Mahaney et al.		
	63	60/511,042	10/14/03	Mahaney et al.		
	64	60/511,002	10/14/03	Mahaney		
	65	60/510,811	10/14/03	Trybulski et al.		
	66	60/510,943	10/14/03	Trybulski et al.		
	67	60/511,001	10/14/03	Mahaney et al.		
	68	60/510,942	10/14/03	Trybulski et al.		

FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO
	69	03/037334	05/08/03	WO		
	70	0 303 961 A1	02/22/89	EP		
	71	0 065 757 A1	12/01/82	EP		

EXAMINER	DATE CONSIDERED
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